UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA NEUROSCIENCE, INC., and YEDA RESEARCH AND DEVELOPMENT CO. LTD., Plaintiffs, v. SANDOZ, INC., SANDOZ INTERNATIONAL GMBH, NOVARTIS AG, and MOMENTA PHARMACEUTICALS, INC., Defendants.	Civil Action No. 08-CV-7611 (BSJ)(AJP) ECF Case
TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA NEUROSCIENCE, INC., and YEDA RESEARCH AND DEVELOPMENT CO. LTD., Plaintiffs, v. MYLAN PHARMACEUTICALS INC., MYLAN INC., and NATCO PHARMA LTD., Defendants.	Civil Action No. 09-CV-8824 (BSJ) (AJP) ECF Case

SANDOZ'S AND MOMENTA'S OPPOSITION TO PLAINTIFFS' MOTION IN LIMINE TO PRECLUDE IMPROPER EXPERT TESTIMONY OF DEFENDANTS' PATENT LAW EXPERT

I. INTRODUCTION

Sandoz Inc. and Momenta Pharmaceuticals, Inc. ("Sandoz") will offer the testimony of PTO expert Eugene C. Rzucidlo on PTO practice and procedure—testimony to which Teva does not object. Teva seeks to exclude his testimony in three areas: legal conclusions on inequitable conduct, the state of mind of the patent applicants, and the materiality of the withheld toxicity data. Sandoz has no intention of offering Mr. Rzucidlo in the first two areas, and had Teva met and conferred with Sandoz prior to filing its motion in limine, much of the motion could have been eliminated. The third area, materiality, is a factual inquiry on which Mr. Rzucidlo can properly testify. In particular, he should be allowed to testify on the factual significance to a PTO examiner of the applicants' misrepresentation/failure to disclose relevant toxicity data. This testimony, which will rely, in part, on the testimony from Sandoz's technical experts, will assist the Court in determining whether the misrepresentation and omission of data were material to patentability. Such testimony is consistent with Fed. R. Evid. 702 and Second Circuit law and will consist of applying PTO practice and procedure to the facts of this case. Teva's motion to block any testimony from Mr. Rzucidlo that touches on the specific facts of this case is illogical, finds no support in the law, and flatly contradicts Teva's own arguments in other cases.

II. ARGUMENT

A. Teva Concedes That Mr. Rzucidlo Is Qualified to Testify About PTO Practice and Procedure

The centerpiece of Mr. Rzucidlo's testimony at trial will be the practices and procedures of the PTO. Teva does not dispute that Mr. Rzucidlo is qualified to testify on this subject matter and does not seek to exclude such testimony. Mr. Rzucidlo worked at the PTO for 15 years, first as a patent examiner in chemical art units and later as an Examiner-In-Chief (Administrative

Patent Judge) on the Board of Patent Appeals and Interferences. (Crystal Decl. Ex. A ¶ 4.) Mr. Rzucidlo is therefore qualified to offer testimony on PTO practice and procedure.

B. Mr. Rzucidlo Should Be Permitted to Testify on the Application of PTO Practice and Procedure to the Facts of This Case

Mr. Rzucidlo's testimony on PTO practice and procedure logically must include application of those procedures to the facts of the case. *See* Fed. R. Evid. 702; *Sanders v. Mount Sinai Sch. of Med.*, 418 F. Supp. 2d 339 (S.D.N.Y. 2005). To hold otherwise, as Teva asks the Court to do, would deprive the Court of a patent examiner's specialized insight into whether Teva followed PTO procedures in procuring the asserted patents. *See IGT v. Alliance Gaming Corp.*, 2008 U.S. Dist. LEXIS 111779, **8-9 (D. Nev. Oct. 21, 2008) (denying motion in limine and permitting defendant's PTO expert to testify "as to whether [plaintiff's] conduct is consistent with patent prosecution procedures").

Teva itself recently argued that its patent expert should be permitted to testify on how PTO practices and procedures "apply to the underlying facts of [the] case so that the Court can better understand how plaintiffs improperly manipulated the patent rules." (Kramer Decl. Ex. 1 at 1).) Teva further argued that "[a] recitation of Patent Office practices and procedures untethered to the particular facts of the case simply would leave the Court to guess which points of expert testimony were relevant to which facts and would not serve Rule 702's goal of helpfulness." (*Id.* at 13.) That logic applies equally here, and Mr. Rzucidlo should be permitted to apply his extensive experience with PTO procedures to the specific evidence in this case.

C. The Court Will Benefit From Mr. Rzucidlo's Testimony on Materiality, Which Is a Question of Fact

Mr. Rzucidlo's expertise in PTO practice and procedure will be particularly helpful to the Court regarding the materiality of the misrepresented/withheld toxicity data. To properly assess materiality, the Court will need to consider the misrepresented/omitted data from the perspective

of a PTO examiner faced with evaluating the patent applications. Mr. Rzucidlo will provide that unique perspective, premised on the opinions of Sandoz's technical experts. Teva offers no legitimate reason to exclude this factual testimony.

In the Second Circuit, "[e]xpert testimony is admissible when it 'will assist the trier of fact to understand the evidence or to determine a fact in issue,'" and the admission of such testimony is "committed to the broad discretion of the District Court." *United States v. Wexler*, 522 F.3d 194, 204 (2d Cir. 2008) (quoting Fed. R. Evid. 702).[1] And because materiality is a question of fact, *J.P. Stevens & Co. v. Lex Tex, Ltd.*, 747 F.2d 1553, 1562 (Fed. Cir. 1984), expert testimony on this issue is appropriate under Second Circuit law. *See Fiataruolo v. United States*, 8 F.3d 930, 941 (2d Cir. 1993) ("Experts may testify on questions of fact as well as mixed questions of fact and law. This sort of testimony is not objectionable merely 'because it embraces an ultimate issue to be decided by the trier of fact.'") (quoting Fed. R. Evid. 704).

To assess the materiality of the omitted data under the *Therasense* "but for" test, the Court must place itself in the position of patent examiner and decide whether the PTO would have allowed the asserted claims if it had been aware of the misrepresented/omitted data.[2] *Therasense, Inc. v. Becton, Dickson & Co.,* 2011 U.S. App. LEXIS 10590, *37 (Fed. Cir. May 25, 2011). In doing so, the Court must apply the preponderance of the evidence standard and

[1] Although the substantive issues of inequitable conduct are governed by Federal Circuit law, the admission of expert testimony is a procedural issue that is governed by Second Circuit law. *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1276 (Fed. Cir. 1999); *Se-Kure Controls, Inc. v. Diam USA, Inc*., 2009 U.S. Dist. LEXIS 1648, *6 (N.D. Ill. Jan. 9, 2009) (citing *Golden Blount, Inc. v. Robert H. Peterson Co*., 438 F.3d 1354, 1358 (2006)).

[2] *Therasense* did not change the standard for inferring specific intent to deceive the PTO. *Therasense*, 2011 U.S. App. LEXIS 10590, *34 ("Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence.") Teva is therefore incorrect that Mr. Rzucidlo applies the wrong legal standard for determining intent. (Mot at 3 n.1.). In any event, Mr. Rzucidlo will not opine on specific intent at trial.

give claims their broadest reasonable construction. *Id.* As a 15-year veteran of the PTO, Mr. Rzucidlo has specialized knowledge applying these standards to patent applications in the chemical arts, including applications for polymers.[3] He is therefore highly capable of assisting the Court in making a determination of materiality under *Therasense*.

Courts have routinely allowed PTO experts to provide this type of factual testimony. *See, e.g.*, *Se-Kure*, 2009 U.S. Dist. LEXIS 1648, at *8 (permitting PTO expert to testify as to materiality of prior art); *Bone Care Int'l LLC v. Pentech Pharms., Inc*., 2010 U.S. Dist. LEXIS 105118, *45-46 (N.D. Ill. Oct. 1, 2010) (permitting PTO expert to provide "factual context that goes to the underlying contentions of inequitable conduct, obviousness, priority, and other key legal issues" and "any extant facts regarding acts or omissions in the applications giving rise to the [asserted] patent"); *Aspex Eyewear, Inc. v. E'Lite Optik, Inc*., 2002 U.S. Dist. LEXIS 14834, *104-105 (N.D. Tex. Apr. 4, 2002) (permitting patent law expert to testify on factual issues of inequitable conduct). Indeed, Teva has often embraced such testimony, for example arguing that its own patent law expert should be permitted to "offer expert opinions and analysis on factual matters relating to inequitable conduct, materiality and intent." (Kramer Decl. Ex. 2 at 9.)

Teva asserts that Mr. Rzucidlo is not qualified to testify regarding materiality, because he has to "rely on technical guys." (Mot. at 4.) Teva fails to recognize that Rule 703 expressly allows an expert to base an opinion on facts and data "made known to the expert." Fed. R. Evid. 703. Such facts and data include the "reports and opinions" of other experts. Advisory Comm.

[3] Teva is far too cute in arguing that Mr. Rzucidlo "was not even an examiner at the PTO in the group to which the applications that resulted in the patents-in-suit were assigned." (Mot at 4.) In his expert report, Mr. Rzucidlo explained that were it not for the pharmaceutical component of the applications, *i.e*., the treatment of multiple sclerosis, "these inventions could have been assigned to the Art Group in which I spent many years serving as a patent examiner." (Crystal Decl. Ex. A ¶ 8.)

Notes to Fed. R. Evid. 703; *Asad v. Cont'l Airlines, Inc*., 314 F. Supp. 2d 726, 740 (N.D. Ohio 2004). Consistent with Rule 703, his opinions regarding toxicity "are based on consultations with other expert witnesses in this case and their expert reports."[4] (Crystal Decl. Ex. A ¶ 9.) And, the technical experts on whose reports he relies—Dr. Kimber and Dr. Rice—will also be testifying. The combination will provide the Court with the expertise and opinions from qualified scientists on the scientific significance of the misrepresented/omitted data and from a veteran PTO examiner on its PTO materiality significance.[5] *See Lemelson v. Gen. Mills, Inc*., No. 77 C 4558, 1987 U.S. Dist. LEXIS 11117, at *2-3 (N.D. Ill. Dec. 1, 1987) (finding patent expert qualified to testify regarding interpretation and application of prior art once technical experts established necessary technical foundation).

III. CONCLUSION

For the foregoing reasons, Teva's motion should be denied.

[4] Likewise, Teva's own patent expert, John F. Witherspoon, relies on Teva's technical experts to support his opinions. (Kramer Decl. Ex. 3 (Witherspoon 3/5/10 Rpt.) ¶¶ 97, 98, 101.)

[5] Teva's reliance on *American Medical Sys., Inc. v. Laser Peripherals, LLC*, 712 F. Supp. 2d 885, 904 (D. Minn. 2010) and *Realtime Data, LLC v. Packeteer, Inc.*, No. 6:08-cv-144, 2009 WL 4545087, at *2 (E.D. Tex. Nov. 19, 2009) is misguided. In neither case did the court hold that a PTO expert could not rely on the testimony of technical experts to provide an informed opinion on the importance of withheld information, as is the case here. Similarly, in *Sundance, Inc. v. Demonte Fabricating Ltd*., 550 F.3d 1356, 1363 (Fed. Cir. 2008), it was an abuse of discretion for a patent law expert to offer technical opinions *of his own*, i.e., not based on other qualified experts, regarding noninfringement and invalidity. That is not the case here, and the Federal Circuit has characterized the *Sundance* case as an "unusual situation." *SEB S.A. v. Montgomery Ward & Co*., 594 F.3d 1360, 1373 (Fed. Cir. 2010).

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s/ Karen L. Hagberg

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